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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,429	MARTANI, ROSA	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Notice of Appeal filed 06/25/03, Request for Continued Examination, Preliminary Amendment filed 08/25/03, and Preliminary Amendment filed 09/03/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/25/03 has been entered.

This is a continuation of applicant's earlier Application No. 10/075,429. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Double Patenting

Non-statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,083,531 ('531). Although the conflicting claims are not identical, they are not patentably distinct from each other because '531 claims a solid pharmaceutical dosage form comprising active substance, filler, binding agent, and usual auxiliaries. The solid dosage form is a quick dissolve formulation, which disintegrates in the mouth within 15 seconds.

Response to Arguments

Applicant's arguments filed 08/25/03 have been fully considered but they are not persuasive. The examiner maintains the double patenting rejection.

Applicant argues that the composition claims (12-26) of the present invention are significantly different and have at least one additional limitation over claims 1-15 of '531. Specifically, the composition claims require the inclusion of a disintegration agent, such as, croscarmellose Na, agents based on sodium carboxymethyl cellulose, poly-N-vinyl-2-pyrrolidones, polymethylmethacrylates, polysaccharides or synthetic resins. In response to the applicant's argument, applicant's attention is drawn to claims 1 and 2 of the '531 reference. The claims require a) active agent, b) filler (sucrose, glucose, fluctose, sorbitol), c) binding agent (starch, cellulose materials, polyvinylpyrrolidones, and alginic acid), wherein the dosage form has density of 200-1000 mg/ml, and disintegrates within 15 seconds. Contrary to the applicant's argument, although the composition of '531 does not specifically recite the term "disintegration agent", the ingredients in the claims such as, sucrose, glucose, fluctose, sorbitol, starch, cellulose materials, polyvinylpyrrolidones, and alginic acid, are the same as the claimed "disintegration agent". Thus, those of ordinary skill would expect a similar quick disintegrate formulation from the use of the instant invention given the claims of '531. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of '531, which set out a similar composition using the same active agent, same filler, same binding agent as claimed herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The "active substance" is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. Step (a)(2) does not require the present of active substance". See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant's specification pages 6, 2nd paragraph, and pages 9-10, disclose dosage form of the invention requires active substance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the other ingredients" in lines 7 and 9. There is insufficient antecedent basis for this limitation in the claim. It appears that the solid dosage form of claim 1 comprising an active substance and other pharmaceutical

ingredients (lines 1-5). There are no "other ingredients" besides active substance and other pharmaceutical ingredients. Further clarification is suggested.

Claim 1 is rejected in the use of step (a)(2). According to applicant's remark on page 3 dated 08/25/03, step (a) could be prepared using the other pharmaceutical ingredients without the active substance. It is confusing because while the claim requires that the dosage form comprising active substance as well as other pharmaceutical ingredients, the steps of the process exclude the use of the active substance. Does this mean that the claimed process is used to prepare: 1) dosage form having active substance, and 2) alternatively, a different dosage form having ***no active substance*** but just other pharmaceutical ingredients? Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Humbert-Droz et al. WO 97/38679.

Humbert-Droz teaches fast disintegrating oral dosage form comprising active agent, filler, binding agent (disintegration agent), and talc as lubricant pages 3-4, and claims 1-13. The dosage form can be a tablet, which disintegrate in the mouth within 15

seconds, and have a density of 200-1000 mg/ml (pages 5-6). The dosage form is prepared without applying any freeze-drying, or any compression force (page 5).

Response to Arguments

Applicant argues that Humbert-Droz fails to include a disintegration agent. Further, applicant submits that binding agents and disintegration agents are not the same compounds and are not interchangeable. Contrary to the applicant's argument, applicant is entitled to be his or her own lexicographer, and in many instances will provide an explicit definition for certain terms used in the claims. Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). Applicant's specification at page 11 defines "disintegration agent" can be any of those known in the art, including croscarmellose Na, polysaccharides, starch...Humbert-Droz teaches the use of sucrose, glucose, fructose, sorbitol, starch, cellulose materials, polyvinylpyrrolidone, and alginic acid (page 3). Accordingly, Humbert-Droz does teach the disintegration agent being claimed. Moreover, applicant's attention is drawn to the disintegration time of Humbert-Droz dosage form, which is within the claimed range, *e.g.*, within 15 seconds. Thus, the 102(b) rejection by Humbert-Droz is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al.

Humbert-Droz teaches process for preparing fast disintegrating oral dosage form discloses in pages 5-6. It appears that Humbert-Droz is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate as claimed in step (c). However, it is the position of the examiner that no criticality is seen in the particular step, since the prior art obtains the same result desire by the applicant, e.g., fast disintegrating oral dosage. Although, Humbert-Droz does not teach compacting the prepared powder or granulate, the extra step does not impart patentability over the applied prior art. Applicant's desire to produce rapidly dissolving dosage form, Humbert-Droz produces rapidly dissolving oral dosage form. Thus, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation modify Humbert-Droz with the expectation of similar result, because Humbert-Droz teaches a rapidly dissolving oral dosage form having the same density and the same disintegrating time. With regarding to the composition claims, it is the position of the examiner that one of ordinary skill in the art would have been motivated to modify Humbert-Droz's composition to obtain the claimed invention because Humbert-Droz teaches a rapidly dissolving oral dosage form having the claimed density of 200-1000 mg/ml, and disintegrating time of within 15 seconds (pages 2-5).

Response to Arguments

Applicant argues that the examiner conclusion is improper, because as illustrated at page 2 of the present specification, the present process assures a uniform content of ingredients, a uniform dosage weight, a less drying time, and the like. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a uniform content of ingredients, a uniform dosage weight, a less drying time, and the like) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The examiner has not been able to determine the unexpected and/or unusual results of the claimed process over that of Humbert-Droz. Applicant's desired is to obtain a rapidly dissolving dosage form, Humbert-Droz uses a similar process to also obtain a rapidly dissolving dosage form desired by the applicant.

Applicant argues that the Examiner's conclusion statement does not establish a rejection under 35U.S.C. 103, and requests withdrawal of the rejection. In response to applicant's argument that the examiner's conclusion of obviousness is based upon

improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicants' claims require a dosage form comprises (1) an active substance, (2) a filler, and (3) a disintegrant. Humbert-Droz teaches a dosage form comprises an active agent, a filler, and a binder selected from starch, cellulose materials, gelatin, polyvinylpyrrolidone, and gum. Although Humbert-Droz does not teach the use of a disintegrant, the binder of Humbert-Droz includes materials similar to the claimed disintegrant. Accordingly, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to, by routine experimentation select a suitable binding agent with the expectation of at least similar result.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone

number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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